

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Black et al ,WO 2004/033445 filed in English on 10-7-2003 and having a provisional US priority date of 10-8-2002. This published application was cited by applicants and is assigned to the same assignee as the instant application.

The reference teaches a fairly broad genus of amides of amino acids. The utility of these compounds is for treating diseases in which inhibition of bone resorption is indicated, such as osteoporosis. Thus the utility is the same as for the compounds of the instant application.

The amide N is substituted with a 3-oxo-azepan-4-yl group. The nitrogen of the 3-oxoazepan-4-yl moiety is preferably substituted with a arylsulfonyl, an aryl(C1-4) alkylsulfonyl, a heteroarylsulfonyl, a heteroaryl(C1-4) alkylsulfonyl, a C3-8cycloalkylsulfonyl, a C3-8cycloalkyl(C1-4) alkyl sulfonyl or a heterocycl(C1-4alkyl) sulfonyl group. See p. 6, line 28 and p. 5, last 3 lines.

A preferred sub-genus of the amino acid moiety of the reference compounds are 2-amino-alkanoic acids with 4-methyl-2-aminopentanoic acid which is leucine being most preferred. See last par. of p. 6 where R3 and R4 are each independently C1-4 alkyl or H and more specifically R3 is isobutyl and R4 is H. More broadly see the fairly narrow definition of R3 and R4 on p.4. There, R3 can be C1-6 alkyl substituted with halo while R4 can be hydrogen.

In instant claim 7, the 3-oxo-azepan-4-yl containing species contain the amide of 4-fluoro-leucine. This occurs in the reference when R3 is 3-fluoro-3-methyl-butyl and R4 is H.

The amino nitrogen is substituted by a haloalkyl or a arylalkyl or a heteroarylalkyl group. In a preferred embodiment R5 is hydrogen and R6 is C1-6 alkyl substituted with 1-6 halo. In a further preferred embodiment R5 is hydrogen and R6 is C1-6 alkyl substituted with 1-6 fluoro. In a further preferred embodiment R5 is hydrogen and R6 is C 1-3 alkyl substituted with 1-3 fluoro. See p.7, lines 4-8.

The instant generic claims are definitely anticipated by the tightly overlapping genera disclosed in the reference.

The species whose synthesis and utility is disclosed by the reference corresponds to the instant claim1 as follows:

The cycloalkanone ring is moiety is [3-oxo-1-(pyridine-2-ylsulfonyl)azepan-4yl].

The amino acid amide moiety is L-leucinamide. Instantly R3 is isobutyl.

Instantly R4 is CF<sub>3</sub>, D and E combine to be 1,1'-biphenyl-4-yl, i.e. p=0, and R5 is 4'-methylsulfonyl.

See page 8, lines 6-9 and p. 33-37 of the reference.

The use of the other agents in the pharmaceutical compositions and methods of treatment are taught by the reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Bernard Dentz/

Primary Examiner, Art Unit 1625